Operations Memo No. 19



VA COOPERATIVE STUDIES PROGRAM # 424

<u>C</u>linical <u>O</u>utcomes <u>U</u>tilizing <u>R</u>evascularization and <u>Aggressive Dru<u>G</u> <u>E</u>valuation</u>

Date: April 6, 2000

From: Pamela Hartigan, PhD, Study Statistician, West Haven CSPCC

Subj: Termination of Partial Reimbursement for Baseline gated Tc-99m Sestamibi (Cardiolite)

Stress Test in COURAGE
To: Study Personnel
Thru: Trial Leadership

• PATIENTS SCREENED, BUT NOT RANDOMIZED

The partial reimbursement of **\$300** (US) for patients screened for eligibility <u>but not ultimately</u> randomized in the COURAGE Trial in one of the following nuclear protocols <u>has been</u> terminated (effective March 31, 2000).

- One-day rest Tc-99m sestamibi /gated stress Tc-99m sestamibi protocol
- One-day rest TI-201/gated stress Tc-99m sestamibi protocol ("dual-isotope protocol")
- Two-day rest Tc-99m sestamibi/gated stress Tc-99m sestamibi protocol

• PATIENTS ENROLLED AND RANDOMIZED

A \$300 (US) partial reimbursement for each baseline gated Tc-99m sestamibi test will be continued for patients who are eligible and ultimately randomized in the COURAGE trial. The Tc-99m sestamibi will continue to be provided by DuPont for all pre-randomized and post-randomized nuclear studies performed throughout the course of the trial. Adenosine provided by Fujisawa will also continue to be available for use if patients are unable to exercise adequately or are consented and enrolled in the nuclear substudy: Short-term Effects of Medical and Interventional Therapy on Ischemic Burden as Determined by Myocardial Perfusion SPECT Imaging in Patients Enrolled in the COURAGE Trial.

If you have any questions about the nuclear substudy or termination of the partial reimbursement for patients screened but ultimately not randomized, please call Kate Hanson, RN at Emory at 404-727-9235.